IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

CARLA SAMMONS, Plaintiff, v. **REGENCE BLUECROSS BLUESHIELD OF OREGON; OREGON BAKERS UNION TRUST FUND; and BOARD OF TRUSTEES, OREGON BAKERS UNION TRUST FUND**, Defendants.	Case No. 3:15-cv-01703-SI **FINDINGS OF FACT AND CONCLUSIONS OF LAW**

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Michael H. Simon, District Judge.

Plaintiff Carla Sammons ("Ms. Sammons") brings this action to challenge the decision made by Defendants Regence BlueCross BlueShield of Oregon ("Regence BCBSO"), Oregon Bakers Union Trust Fund, and the Board of Trustees of Oregon Bakers Union Trust Fund (the "Board") (collectively "Defendants") denying medical benefits under the Oregon Bakers Union Health and Welfare Trust Fund Plan 4 (the "Plan") on the grounds that the requested medical procedure was "Investigational." Ms. Sammons argues: (1) her procedure was not Investigational under the Plan; (2) even if the procedure were Investigational, it still should have been covered under the "Alternative Benefits" section of the Plan; and (3) by paying a portion of the expenses

of the procedure, the Plan has waived its right to argue that it may not pay the remainder. Defendants respond that Ms. Sammons's medical procedure was "Investigational," as defined by the Plan, because the scientific evidence has not yet permitted a conclusion regarding the long-term efficacy and safety of artificial discs, in comparison to recognized alternatives. Defendants add that the Alternative Benefits provision of the Plan have not been triggered and that no waiver has occurred. After a bench trial on an administrative record, the Court concludes that Ms. Sammons is not entitled to the requested benefits under the Plan.

STANDARDS AND PROCEDURE

The Employee Retirement Income Security Act ("ERISA") provides that an ERISA plan "participant" may bring a civil action in federal court "to recover benefits due to him under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan[.]" 29 U.S.C. § 1132(a)(1)(B); *Metro. Life Ins. Co. v. Glenn*, 554 U.S. 105, 108 (2008) ("[ERISA] permits a person denied benefits under an employee benefit plan to challenge that denial in federal court."). An ERISA plan that does not contain text conferring discretion on the plan administrator is subject to a *de novo* standard of review. *Metro. Life Ins.*, 554 U.S. at 111 (citing *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 115 (1989)). The Plan at issue in this lawsuit does not confer discretion on the Plan administrator. AR00001-00103. Further, the parties have agreed that a *de novo* standard of review applies in this case. Dkts. 14 at 6-7; 17 at 8. The court accepts the parties' stipulation and thus reviews the record *de novo*. *See Rorabaugh v. Cont'l Cas. Co.*, 321 F. App'x 708, 709 (9th Cir. 2009) (court may accept parties stipulation to *de novo* review).

Under *de novo* review, the trial court does not give deference to the Plan administrator's rationale or determination. *Mongeluzo v. Baxter Travenol Long Term Disability Benefit Plan*,

46 F.3d 938, 943 (9th Cir. 1995). Instead, the trial court performs an "independent and thorough inspection" of the Plan administrator's decision to determine whether the Plan administrator correctly or incorrectly denied benefits. *Silver v. Exec. Car Leasing Long-Term Disability Plan*, 466 F.3d 727, 733 (9th Cir. 2006). *De novo* review permits the trial court to "evaluate the persuasiveness of conflicting testimony and decide which is more likely true." *Kearney v. Standard Ins. Co.*, 175 F.3d 1084, 1095 (9th Cir. 1999) (en banc).

Ms. Sammons has filed a motion for summary judgment. Dkt. 14. Defendants have cross moved for judgment based on a bench trial on an administrative record. Dkt. 17, at 8. In addition, the parties have filed a stipulated motion to supplement the administrative record (Dkt. 13), and the Court has granted that motion. Dkt. 16. The appropriate procedure to resolve this dispute is through a bench trial on an administrative record, as supplemented, pursuant to the parties' stipulation. *See Rabbat v. Standard Ins. Co.*, 894 F. Supp. 2d 1311, 1314 (D. Or. 2012); *see also Casey v. Uddeholm Corp.*, 32 F.3d 1094, 1099 (7th Cir. 1994) (on *de novo* review of an ERISA benefits claim, the "appropriate proceeding[ ] . . . is a bench trial and not the disposition of a summary judgment motion"); *Lee v. Kaiser Found. Health Plan Long Term Disability Plan*, 812 F. Supp. 2d 1027, 1032 n.2 (N.D. Cal. 2011) ("*De novo* review on ERISA benefits claims is typically conducted as a bench trial under Rule 52."); *but see Orndorf v. Paul Revere Life Ins. Co.*, 404 F.3d 510, 517 (1st Cir. 2005) ("When there is no dispute over plan interpretation, the use of summary judgment . . . is proper regardless of whether our review of the ERISA decision maker's decision is de novo or deferential."). Further, in a trial on an administrative record:

> The district judge will be asking a different question as [the judge] reads the evidence, not whether there is a genuine issue of material fact . . . . In a trial on the record, but not on summary judgment, the judge can evaluate the persuasiveness of conflicting testimony and decide which is more likely true.

Kearney, 175 F.3d at 1095.

The Court has reviewed the administrative record, as supplemented by stipulation of the parties, and has made factual findings under a preponderance of the evidence standard. Pursuant to Rule 52(a), the Court issues the following findings of fact and conclusions of law based on the supplemented administrative record and the parties' arguments.

FINDINGS OF FACT

A. Background

1. Ms. Sammons is approximately 55 years old. She has a history of lower back pain and degenerative disc disease in her lumbar spine. AR00202. Degenerative disease is an "illness resulting from aging, repetitive injury, or other pathological causes." *Taber's Cyclopedic Medical Dictionary* 593 (Donald Venes et al. eds. 2009) [hereinafter *Taber's*].

2. Ms. Sammons was, at all material times, a beneficiary under the Oregon Bakers Union Health and Welfare Trust Fund Plan 4 (the "Plan") through her spouse's employment by Franz Bakery.

3. On December 13, 2011, a Level 1 Lumbar Discogram revealed a Grade IV Fissure in Ms. Sammons's L5-S1 disc; that the disc was abnormal, severely degenerative, and sclerotic;[1] and that pressurization produced severe concordant pain. AR00213-216. Ms. Sammons rated her pain a ten on a scale of one to ten. *Id*. On March 13, 2013, a lumbar spine MRI showed Ms. Sammons's L5-S1 advanced disc space narrowing, disc bulging, mild facet arthrosis,[2] and spondylosis[3] encroachment upon the interior foramina[4] resulting in mild

[1] "Sclerotic" is the adjective form of "sclerosis," which means :[a] hardening or induration of an organ or tissue, esp. that due to excessive growth or fibrous tissue." *Taber's Cyclopedic Medical Dictionary* 2085 (Donald Venes et al. eds. 2009).

[2] "Arthoris" is "[a] joint disorder caused by trophic degeneration." *Taber's at* 193.

[3] "Spondylosis" is a vertebral condition. *Taber's* at 2183.

[4] "Foramina" are "hole[s] in a bone for passage of vessels or nerves." *Taber's* at 894.

bilateral narrowing. AR00239-243. During a March 25, 2013 office visit with Richard Guyer M.D., Ms. Sammons reported lower back pain with bilateral leg pain and numbness and giving way of the left leg, which she had suffered from for the last three years. AR00202-207. Based upon previous discussions with Dr. Guyer, Ms. Sammons requested total disc arthroplasty, *i.e.* artificial disc replacement surgery (the "Surgery"), which was scheduled for June 27, 2013. AR00202-207.

4. On June 7, 2013, Ms. Sammons sought pre-authorization from defendant Regence for the Surgery by completing and faxing to Regence its "Pre-Authorization Request Form." AR00356. Regence denied Ms. Sammons's pre-authorization request on the grounds that "[t]he scientific evidence doesn't sufficiently conclude that lumbar artificial diskectomy improves health outcomes," AR00191, and therefore the requested Surgery is "Investigational," as defined by the Plan.[5] AR00075. Notwithstanding this conclusion, the Plan later paid $1,012.50 to Pinnacle Anesthesia Consultant for the anesthesia services that Ms. Sammons received during the Surgery. Dkt. 15-1 at 6.

5. Despite Regence's denial, Ms. Sammons underwent the Surgery as scheduled on June 27, 2013. AR00231-32. The Surgery was successful in reducing Ms. Sammons's lower back pain, although she continued to suffer from upper back and left arm pain and numbness. AR00254-56. X-rays showed that her disc now was in good position at L5-S1. *Id.*

6. Ms. Sammons appealed the Plan's denial four times. She appealed twice to Regence BCBSO and once to an independent review organization ("IRO") selected by the Oregon State Insurance Division. Finally, she appealed to the Oregon Bakers Union Trust Board of Trustees.

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[5] Regence's original pre-authorization denial is not in the record.

7. "Barbara D.," from patient financial services at Texas Health Partners, Ms. Sammons's surgical provider, submitted the first appeal of claim denial to Regence on August 16, 2013. AR00121. The submission consisted of the provider's medical records for the surgery, but omitted any treatment records before the surgery. At Regence BCBSO, Robert Manley, M.D., reviewed the first appeal and determined that the Surgery was an "investigational" procedure, under the Regence Medical Policy ("Medical Policy"). AR00186-189. Regence then informed Ms. Sammons of the denial and her right to appeal further. AR00191-193.

8. Ms. Sammons submitted her second appeal to Regence on February 12, 2014. AR00195-196. This submission consisted of the L5-S1 Operative Report, discogram, MRI, surgical documentation, letter of medical necessity from Dr. Guyer, Ms. Sammons's complete medical records from the Texas Back Institute, and selected articles on artificial discs. AR00194-00327. Kim Sloan, M.D., an outside reviewer and orthopedic surgeon with a special expertise in spine surgery, was engaged by Regence to review the second appeal. AR00335. Dr. Sloan also determined the artificial disc implant fell within the investigational exclusion. *Id.* She further stated that the current peer-reviewed literature "has not shown significant advantage of artificial disc replacement compared to the standard of care, which is fusion. While the artificial disc may have increased motion, the reoperation rate is higher [1, 2]." AR00334. Dr. Sloan then cited to the Regence Medical Policy Manual and additional published medical literature. AR00335. Based upon this review, Regence BCBSO denied Ms. Sammons's appeal and informed her of her right to initiate an "external review" of the denial by making a request to either Regence BCBSO or to the Oregon Department of Consumer and Business, Insurance Division ("DCBS"). AR00342-345.

9. On August 25, 2014, Ms. Sammons submitted a request for external review. AR00348. This submission consisted of medical records and the same articles submitted in the second appeal. AR00348-443. On August 28, 2014, DCBS notified Regence BCBSO that DCBS had selected IPRO in Lake Success, New York, as the external reviewer. AR00447-448. The IPRO external review was performed by a physician in active practice, board certified in orthopedic surgery, and with a fellowship in spine surgery. AR00453. On September 24, 2014, IPRO issued a decision upholding the Regence BCBSO denial. AR00453-456. In a summary "Analysis and Rationale," the IPRO Medical Director, Monty M. Bodenheimer, M.D., explained that the "use of artificial discs looks promising for future treatment of lumbar disc pathology; however, the treatment is still considered investigative. The short-term outcome of TDR is at least equivalent to fusion surgery. Long-term efficacy and safety of the devices has yet to be established." AR00455.

10. On February 23, 2015, Ms. Sammons submitted her fourth and final appeal to the Board of Trustees of the Oregon Bakers Trust Fund (the "Board"). AR00467-468. On March 17, 2015, the Board denied the final appeal, finding that both Regence and the Independent Review Organization reasonably concluded that the Surgery was investigational. AR00464-466.

11. The Plan does not provide coverage for "investigational" services. AR00035-36. "Investigational" is defined as:

> A Health Intervention that We have classified as Investigational. We will review Scientific Evidence from well-designed clinical studies found in peer-reviewed medical literature, if available, and information obtained from the treating Physician or Practitioner regarding the Health Intervention to determine if it is Investigational. A Health Intervention not meeting all of the following criteria, is, in Our judgment, Investigational:
>
> [1] If a medication or device, the Health Intervention must have final approval from the U. S. Food and Drug Administration as being safe and efficacious for general marketing. . . .

> [2] The Scientific Evidence must permit conclusions concerning the effect of the Health Intervention on Health Outcomes, which include the disease process, Injury or Illness, length of life, ability to function and quality of life.
>
> [3] The Health Intervention must improve net Health Outcome.
>
> [4] The Scientific Evidence must show that the Health Intervention is as beneficial as any established alternatives.
>
> [5] The improvement must be attainable outside the laboratory or clinical research setting.

AR00075.

12. The Plan also provides for payment of "Alternative Benefits" as follows:

> Alternative benefits means benefits for services or supplies that are not otherwise covered under the Contract, but for which We may approve coverage after case management evaluation and analysis. We may cover alternative benefits through case management if We determine, in our sole discretion, that alternative benefits are Medically Necessary and will result in overall reduced covered costs and improved quality of care. Before coverage of alternative benefits and before the processing of claims for alternative benefits, We, You or Your legal representative and, if required by Us (in Our sole discretion), Your Physician or other Provider must agree in writing to the specific terms and conditions for payment. Alternative benefits are approved on a case-specific basis only.

AR00041.

13. The Plan defines "Medically Necessary" as follows:

> [H]ealth care services or supplies that a Physician or other health care Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease, or its symptoms, and that are: [1] in accordance with generally accepted standards of medical practice; [2] clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury or disease; and [3] not primarily for the convenience of the patient, Physician or other health care Provider, and not more costly than an alternative service or sequence of services or supply at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease. For these purposes, "generally accepted

> standards of medical practice" means standards that are based on credible Scientific Evidence published in Peer-Reviewed Medical Literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians and other health care Providers practicing in relevant clinical areas and any other relevant factors.

AR00076.

14. The Plan defines "Scientific Evidence" as:

> scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff; or findings, studies or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes. However, Scientific Evidence shall not include published peer-reviewed literature sponsored to a significant extent by a pharmaceutical manufacturing company or medical device manufacturer or a single study without other supportable studies.

AR00076-77.

15. The Plan defines "Health Intervention" as:

> medication, service or supply provided to prevent, diagnose, detect, treat or palliate the following: disease, Illness, Injury, genetic or congenital anomaly, pregnancy or biological or psychological condition that lies outside the range or normal, age-appropriate human variation; or to maintain or restore functional ability. A Health Intervention is defined not only by the intervention itself, but also by the medical condition and patient indications for which it is being applied. A Health Intervention is considered to be new if it is not yet in widespread use for the medical condition and the patient indications being considered.

AR00074-75.

16. The Plan defines "Health Outcome" as "an outcome that affects health status as measured by the length or quality of a person's life. The Health Intervention's overall beneficial effects on health must outweigh the overall harmful effects on health." AR00075.

B. Whether Artificial Disc Replacement Surgery Is "Investigational"

18. The parties do not dispute the meaning of the Plan's terms. Under the Plan, a medical procedure must satisfy five criteria to avoid classification as "Investigational." AR00075. The Plan requires that *all* criteria must be satisfied. Thus, a failure to meet even one of the criteria will result in a finding that the Health Intervention is investigational. *Id.*

19. The parties also do not dispute that the first and fifth criteria are satisfied. The artificial disc device has final approval from the United States Food and Drug Administration as being safe and efficacious for general marketing (the first criterion) and the improvement was attainable outside the laboratory or clinical research setting (the fifth criterion). While Defendants do not stipulate that the Surgery performed on Ms. Sammons did in fact improve net Health Outcome (the third criterion), the parties do not focus on that issue. The parties primarily dispute whether there exists (a) scientific evidence permitting conclusions concerning the effect of lumbar total disc replacement on health outcomes (the second criterion) and (b) scientific evidence showing lumbar total disc replacement is as beneficial as any established alternative (the fourth criterion). *See* ¶ 11 (Findings of Fact, Background), *supra*.

1. Whether the Scientific Evidence permits conclusions regarding the effect of disc replacement on net health outcomes (the second criterion)

20. Regence BCBSO reviewed and updated its Medical Policy on artificial discs in February 2013, approximately four months before Ms. Sammons's surgery. AR00104-120. The updated Medical Policy concludes that the "Scientific Evidence" was "insufficient to permit conclusions about the long-term benefits and safety of total disc replacement with artificial intervertebral discs ("TDR"). AR00106. In support of this conclusion, the Policy addresses five concerns with the state of the Scientific Evidence. These concerns are: (1) insufficiency of data to adequately establish long-term safety and effectiveness of the discs in the treatment of

degenerative disc disease; (2) lack of knowledge regarding long-term performance, durability, revisability, and complication rates; (3) existence of only one evidence-based clinical practice guideline from U.S. neurosurgery or orthopedic professional associations;[6] (4) each of the randomized trials on which the FDA approval was based was limited to two-year outcomes and all studies demonstrating the 5-year data were not available at that time; and (5) lack of demonstration of potential benefits and uncertainty regarding whether response rates will decline over time. *Id.* The Medical Policy also notes that long-term data is necessary because patterns of degenerative changes following TDR or fusion take at least five years to become measurable, the benefits of spinal surgery are known to deteriorate over time, and complications of spinal surgery tend to increase over time. AR00107. Moreover, the IPRO external review, in upholding the Regence BCBSO denial, explained that artificial disc replacement is "comparable to the lumbar fusion at two year followup. However, long term efficacy and safety of the devices cannot be established." AR00455. Thus, to permit conclusions concerning the effect of artificial disc replacement surgery on health outcomes, the scientific evidence must address outcomes at least five years after surgery.

21. Ms. Sammons initially submitted five articles on artificial disc replacement treatment in support of her arguments. AR00276-325. Under the "Investigational" exclusion, the reviewer is directed to consider scientific evidence from well-designed clinical studies found in peer-reviewed medical literature and information obtained from the treating physician. Specifically, "Scientific Evidence," as defined above, consists of scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements and

[6] "The North American Spine Society (NASS) guidelines for cervical radiculopathy noted that short-term outcomes suggested TDR and fusion are comparable . . . but these outcomes must be validated in long-term studies." AR00106.

are peer-reviewed, and findings conducted by federal government agencies and nationally recognized federal research institutes. Scientific Evidence does not include, however, any published peer-reviewed literature that are sponsored to a significant degree by a pharmaceutical manufacturing company or medical device manufacturer or a single study without other supportable studies. AR00076-77.

22. First, Ms. Sammons submits an article discussing the results of the randomized, multicenter FDA study comparing ProDisc-L total disc replacement with circumferential fusion, the established alternative to artificial disc replacement.[7] AR00278-285. The study treated 286 patients, evaluating them before and after surgery at 6 weeks and at 3, 6, 12, 18, and 24 months. The study concluded that the ProDisc-L was safe, efficacious, and "superior to circumferential fusion by multiple clinical criteria." AR00278. Specifically, the study demonstrated that at 24 months, the ProDisc-L patients had 51 percent improvement in visual analog scale ("VAS") pain, 46 percent improvement from baseline Oswestry Disability Index ("ODI"), and significantly higher VAS satisfaction and neurological status than fusion patients. AR00285.

23. Second, Ms. Sammons submits an article entitled "ProDisc Retrospective Clinical Study: 7 to 11 Year Follow-Up." AR00276-277, 286-297, 311-313. This article has not been published, or accepted for publication, by any medical journals and thus cannot be considered under the Plan's definition of "Scientific Evidence." The Court does not consider this article.

24. Third, Ms. Sammons submits an article entitled "Minimally invasive total disc replacement: surgical technique and preliminary clinical results," AR00298-302, which considered a nonrandomized study of 34 patients with an average age of 44 years. AR00301. Patients were evaluated before and after surgery at 3, 6, 12, and 24 months. *Id.* The study found

[7] Circumferential fusion is the surgical standard of care and the established alternative to artificial disc replacement. AR00278, 329.

major advantages to disc replacement such as its standardized, minimally-invasive approach and quick recovery time, with patients able to get out of bed the day after surgery. AR00302. The article concluded that, "although preliminary, the results suggest, that total disc replacement for the indications mentioned above might be a reasonable alternative to lumbar fusion." *Id.*

25. Fourth, Ms. Sammons submits an article entitled "Lumbar Total Disc Replacement. Seven to Eleven-Year Follow-Up," AR00303-310, which addresses the same study as the unpublished article cited above. The article was co-authored by Dr. Thierry Marnay, the inventor of the ProDisc, and published in the Journal of Bone & Joint Surgery in 2005. AR00303. Of the 64 patients treated, 55 had sufficient follow-up, with a mean duration of follow-up at 8.7 years. AR00304. The results showed that at approximately 8.7 years after surgery, 33 had excellent results, 8 had good results, and 14 had poor results. *Id.* The study concluded that ProDisc lumbar total disc replacement appears to be safe and effective in treatment yet stressed the need for randomized trials and validation:

> The current study had all of the limitations inherent to nonrandomized case series. We cannot make any definitive statements regarding the outcomes of lumbar total disc replacement compared with those of nonoperative treatment or arthrodesis [fusion]. The data reflect the results associated with a single implant type and may be different for other designs… Furthermore, the study would be more useful if validated outcomes instruments had been used. Nevertheless, our data indicate that the prosthesis is safe, with an acceptably low rate of complications at seven to eleven years postoperatively, and that its efficacy appears promising and should be tested in a randomized prospective trial.

AR00309.

26. Fifth, Ms. Sammons submits an article entitled "Long-term Results of One-Level Lumbar Arthroplasty," AR00314-319, which describes a study of 108 patients with a mean age of 36.4 years. AR00314-315. All patients were seen for a clinical follow-up at 3 and 6 months, and at 1, 5, and 10 years. AR00315. Also, 10 patients were followed for 15 years after surgery.

Id. The study found that the "[c]linical outcomes and the rate of return to work were excellent overall. The rate of adjacent-level disease requiring surgical intervention was considerably lower (2.8%) compared with . . . lumbar fusion."[8] AR00319. These results, the study notes, demonstrate the safety and efficacy of artificial disc replacement surgery over the long term.

27. Defendants argue that the articles and studies submitted by Ms. Sammons do not alter the conclusions in the Medical Policy or made by the reviewers. Of the five studies described above, only one is a randomized clinical trial, most note an inability to make definitive statements regarding outcomes, and all fail to present long-term results based on a randomized trial or study. According to Defendants, a post-operative follow-up study of five years is needed to assess long-term effects due to the special nature of spinal surgery, with benefits deteriorating over time and degenerative changes taking at least five years to manifest. In support of these contentions, Defendants cite to the Regence Medical Policy Manual. AR00106-107.

28. The Plan requires that the scientific evidence must permit conclusions concerning the effect of the Surgery on "Health Outcomes, which include the disease process, Injury or Illness, length of life, ability to function and quality of life." AR00075. Of the four reviewable studies cited by Ms. Sammons, only one was a randomized clinical trial. AR00278-285. A randomized clinical trial is an "experimental study to assess the effects of a particular variable (for example, a drug or treatment) in which subjects are assigned randomly to an experimental, placebo, or control group. . . . Members of each group are prevented from knowing whether they are receiving the active therapy. The researchers gathering the data are also typically blinded to

[8] Additionally, in comparing replacement surgery with fusion procedures, the study notes "[f]or fusion procedures . . . 'complications' [such as subsequent reoperations at the index-level or the adjacent-level] are rarely reported because in most cases the follow-up is limited to 2 years, sometimes less. The rate of complications in this series is acceptable in comparison to . . . fusion studies." AR00318.

group assignment." *Taber's* at 1969. The use of randomization in research allows clinicians "to assign subjects to experimental groups without introducing biases into a study." *Id.*

29. The sole randomized study, the FDA comparison of ProDisc-L total disc replacement with circumferential fusion, reviewed patients with a final follow-up date at 24 months from the time of surgery. AR00278. Although this study concluded that total disc replacement was superior to circumferential fusion at 24 months, it cannot make any conclusions regarding success rates, complications, or reoperation rates beyond this period of time. *Id.* According to the Regence BCBSO Medical Policy, patterns of degenerative changes following TDR or fusion take at least five years to become measurable. AR00107. This is due to the special nature of spinal surgery, the benefits of which are known to deteriorate over time. *Id.* The IPRO external reviewer, in finding artificial disc replacement to be "Investigational" under the terms of the Plan, emphasized the lack of long-term scientific evidence and stated that even though the current literature indicates that artificial disc replacement is comparable to fusion at two year follow-up, the "long term efficacy and safety of the devices cannot be established." AR00455. Moreover, Dr. Sloan, the independent reviewer of Ms. Sammons's second appeal, explained: "While the artificial disc may have increased motion, the reoperation rate is higher." AR00334 (footnotes omitted). Therefore, the only randomized study cited by Ms. Sammons demonstrates a time period that is too short to draw conclusions regarding the effect of total disc replacement surgery on disease process, injury, length of life, ability to function, and quality of life beyond a 24-month period.[9] Ms. Sammons encounters a similar problem with respect to article three,

[9] On March 15, 2016, Ms. Sammons submitted a supplemental article entitled "Comparison of Artificial Total Disc Replacement Versus Fusion for Lumbar Degenerative Disc Disease: A Meta-Analysis of Randomized Controlled Trials." *See* Dkt. 21-1. The Court may exercise its discretion to consider evidence beyond the administrative record "*only* when circumstances *clearly establish* that additional evidence is *necessary* to conduct an adequate de novo review of the benefit decision." *Opeta v. Nw. Airlines Pension Plan for Contract Emps.*, 484 F.3d 1211, 1217 (9th Cir. 2007) (emphasis in original) (quotation marks and citation omitted). The Ninth Circuit has also emphasized that district courts should not consider additional evidence "merely because someone at a later time comes up with new

"Minimally invasive total disc replacement: surgical technique and preliminary clinical results," because it is a nonrandomized study with a final follow-up date at 24 months. AR00298-302.

30. In an attempt to display the benefits of total disc replacement surgery beyond 24 months, Ms. Sammons submits two articles. The first of these, "Lumbar Total Disc Replacement. Seven to Eleven-Year Follow-Up," was a nonrandomized study with a mean postoperative follow-up date at 8.7 years. Although the study had approximately a 75 percent success rate, the study itself emphasized that the reviewers "cannot make any definitive statements regarding the outcomes of lumbar total disc replacement compared with those of nonoperative treatment or arthrodesis." AR00309. Although the Regence BCBSO Medical Policy stated that there are 23 types of artificial disc either approved or seeking the approval of the FDA, the study considered only one implant type. AR00104-105, 309. The reviewers themselves conclude that the prosthesis "should be tested in a randomized prospective trial." AR00309. Thus, this study does not allow a conclusion to be drawn regarding the effect of the Surgery on net health outcomes.

31. The second long-term study, "Long-term Results of One-Level Lumbar Arthroplasty," was a nonrandomized study with a final postoperative follow-up date at 10 years, with 10 patients being followed for 15 years. AR00314-315. This study also reviewed a single type of artificial disc, the Charité Artificial Disc, which was withdrawn from the market and has been the subject of several products liability lawsuits. AR00105; *see e.g., Miller v. DePuy Spine, Inc.* 638 F.Supp.2d 1226 (D. Nev. 2009); *Carson v. Depuy Spine, Inc.* 2007 WL 1839324 (C.D.

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evidence." *Id.* This article is not new evidence because it was published before Ms. Sammons underwent the Surgery. Ms. Sammons could have submitted the article when she submitted the other five articles in the appeal process. Moreover, the article does not present new scientific evidence that would affect the outcome of Ms. Sammons's claim determination. This article also repeated the scientific evidence already contained in the administrative record. Specifically, the article reiterates that the Surgery has been studied under randomized controlled trials with only 24 months follow up and that long-term follow-up in a randomized trial is necessary to evaluate the efficacy and safety of the Surgery. Ms. Sammons has not "clearly established" that this article is "necessary" to the Court's de novo review. Thus, the court does not consider this article on de novo review.

Cal. June 21, 2007). Therefore, the Court finds that the study is not persuasive scientific evidence to support Ms. Sammons's claim against Defendants.

32. Plaintiff also introduces evidence of treating physician Dr. Guyer's support for artificial disc replacement surgery.[10] AR00340-341. Defendants argue that this information is immaterial to an "Investigational" determination because it does not constitute "Scientific Evidence" under the Plan. The Plan's definition of "Investigational," however, explicitly states that the reviewer "will review Scientific Evidence . . . *and* information obtained from the treating Physician or Practitioner regarding the Health Intervention to determine if it is Investigational." AR00075 (emphasis added). Therefore, Dr. Guyer's remarks regarding the safety and efficacy of artificial disc treatment are appropriate and material.

33. Dr. Guyer's letter states, "I feel that arthroplasty with ProDisc is a better choice of treatment for my patient than spinal fusion…. and feel that it is medically necessary." AR00341. Dr. Guyer summarized the disadvantages of spinal fusion such as its permanent and irreversible nature, prolonged recovery time, variable success rates, and loss of motion of the fused spinal segment that may result in increased stress and load at adjacent levels. AR00340. Dr. Guyer concluded that replacement surgery using the ProDisc is advantageous because it preserves normal motion of the operative spinal segment, improves segmental stability, restores disc height, reestablishes lordotic alignment, reduces discogenic pain, potentially reduces adjacent level degeneration, requires a shorter hospital stay, and allows for more rapid rehabilitation and return to function and work. *Id.*

34. Although Dr. Guyer presents a strong argument in support of the merits of artificial disc replacement surgery and the ProDisc device, Ms. Sammons's proffered "Scientific

[10] The Record also appears to contain an unsigned copy of an identical letter from Jack Zigler, M.D., another co-director at Texas Back Institute. AR00337-338.

Evidence" fails to support a conclusion regarding the effect of the Surgery on "net health outcomes." As the IPRO Medical Director, Dr. Bodenheimer explained, the "use of artificial discs looks promising for future treatment of lumbar disc pathology; however, the treatment is still considered investigative. . . . Long-term efficacy and safety of the devices has yet to be established." AR00455. The data put forward by Ms. Sammons does not contain necessary long-term data as of this time and therefore does not permit a conclusion regarding the effects of artificial disc replacement surgery on net health outcomes.[11]

2. Whether the Scientific Evidence shows that disc replacement is as beneficial as any established alternative (the fourth criterion)

35. For the same reasons that the scientific evidence submitted does not show the required conclusions regarding net health outcomes, that evidence also does not show that the Surgery is as beneficial as any established alternative. Ms. Sammons's scientific evidence permits the conclusion that lumbar spine arthroplasty procedures are at least equivalent to circumferential fusion in short-term results. AR00278, 285. Long-term results, however, have not yet been shown. Because the proffered data does not permit a conclusion regarding the effect of the surgery on net health outcomes, it similarly does not permit a conclusion regarding whether the surgery is equivalent to fusion. Therefore, the Court cannot state with any reasonable degree of confidence that this method is as beneficial as any established alternative. Accordingly, the Court finds, by a preponderance of the evidence, that artificial disc replacement surgery is not "Investigational" under the terms of the Plan.

[11] The evidence submitted to supplement the administrative record consists of documents Ms. Sammons sent to the Oregon Bakers Union Health and Welfare Trust. The documents include references to a number of studies not otherwise discussed in the parties' briefing. These studies do not alter the Court's finding that Ms. Sammons has not presented sufficient evidence regarding the effects of artificial replacement surgery on net health outcomes. The studies either do not follow up with patients more than 24 months after surgery or contain qualifying statements such as "the evidence of efficacy should not be generalized beyond carefully selected patients that match trial and FDA indications," Dkt. 13 at 30, and "the quality (risk of bias) of this trial was 'poor,'" *id.* at 44.

C. Whether There Is Coverage Under the Plan's "Alternative Benefits" Provision

36. Ms. Sammons also argues that even if her Surgery is not covered based on the investigational exclusion, the Plan should have provided coverage under its "Alternative Benefits" provision. Under the alternative benefits provision in the Plan, Regence BCBSO may approve coverage "for services or supplies that are not otherwise covered under the Contract." AR00041. This provision states that Regence BCBSO "may approve coverage after case management evaluation and analysis." *Id.* The provision further states that the Plan "may cover alternative benefits through case management if [Regence BCBSO] determine[s], in [its] sole discretion, that alternative benefits are Medically Necessary and will result in overall reduced covered costs and improved quality of care." *Id.* The Plan notes, however, that "[b]efore coverage . . . and . . . the processing of claims for alternative benefits," Regence BCBSO, Ms. Sammons or her legal representative, and if required by Regence BCBSO in its sole discretion, Ms. Sammons's physician or other provider, "must agree in writing to the specific terms and conditions for payment." *Id.* Defendants contend that Ms. Sammons never participated in case management and that the parties never came to a written agreement regarding terms and conditions for payment. Therefore, according to Defendants, the Surgery could not have been covered by the alternative benefits provision. Ms. Sammons argues that the Surgery was medically necessary and therefore should have been covered under this provision in the Plan.

1. Case Management

37. According to Ms. Sammons, Defendants improperly denied Ms. Sammons's pre-authorization request and should have conducted case management. The Plan explains that a member of the Plan may request case management or that a case manager may be assigned to a particular Plan member and lists a case management phone number. AR00007. The Plan

explicitly states that Regence BCBSO has, in its sole discretion, the authority to cover alternative benefits only "after case management evaluation and analysis."

38. Ms. Sammons asserts that by submitting the Pre-Authorization Form, she initiated a request for case management assessment. There is no evidence, however, that submitting a Pre-Authorization Form is a proper method to initiate case management. There is also no evidence in the record that Ms. Sammons ever called the number listed in the Plan to request a case manager. Further, there is no evidence that Regence BCBSO ever exercised its sole discretion as part of a case management process in Ms. Sammons's case. Finally, there is no evidence of a written agreement to the specific terms and conditions for payment, which also is required under the alternative benefits provision in the Plan.

39. The Regence BCBSO Medical Policy also describes the requirements for covering alternative benefits. Ms. Sammons did not comply with these requirements and thus never triggered Regence BCBSO's discretion to provide alternative benefits through case management evaluation and analysis. Thus, the Surgery never became eligible for coverage under the alternative benefits provision.

2. Medically Necessary

40. Ms. Sammons argues that the Plan covers the Surgery under the Alternative Benefits provision because it was medically necessary and would result in reduced costs and improved quality of care compared to fusion. Because the Court finds that the Surgery never became eligible for coverage through a case management process under the Plan, there is no need to assess the medical necessity of the Surgery under the Alternative Benefits provision.

D. Whether Regence BCBSO Waived the Plan's Investigational Exclusion by Paying the Anesthesiology Bill after the Surgery

41. Ms. Sammons argues that by paying for the anesthesiology bill in connection with the Surgery, Defendants have waived nonpayment of the rest of the Surgery bill.[12]

42. Regence BCBSO Medical Policy, updated several months before Ms. Sammons's Surgery, expressly provides that total disc replacement with artificial intervertebral discs was Investigational and therefore is not covered under the Plan. AR00104.

43. The record does not indicate precisely when Ms. Sammons received the decision denying her first request for pre-authorization, but Ms. Sammons admits that she knew that her pre-authorization request was denied before her Surgery and that she went ahead with the Surgery with that knowledge.

44. Regence has consistently maintained, through each denial of coverage and through its medical policy, that it had no intention of covering the Surgery because it fell within the Plan's "Investigational" exception. Further, Ms. Sammons does not argue that she relied on her receipt of the post-surgery payment for anesthesiology services to support any assumption that Regence BCBSO would reverse its intention under its Medical Policy not to cover the Surgery or in any other way relied on that payment to her detriment.

CONCLUSIONS OF LAW

1. Based on the Court's factual findings that Plaintiff's artificial disc replacement Surgery is Investigational under the terms of the Plan, Defendants are not obligated to provide coverage for that procedure.[13]

[12] Ms. Sammons does not specify whether the alleged waiver was express or implied. Because there is no evidence in the record of any express waiver from Regence BCBSO for the Surgery, the Court assumes that Ms. Sammons is arguing for the Court to find an implied waiver based on its post-surgery partial payment.

[13] The claimant must establish by a preponderance of the evidence that he or she is entitled to benefits under the plan. *See Muniz*, 623 F.3d at 1294; *Inciong v. Fort Dearborn Life Ins. Co.*, 570 F. App'x 724, 725 (9th Cir. 2014). In

2. Based on the Court's factual findings that Plaintiff did not satisfy the requirements for receiving coverage under the "Alternative Benefits" provision of the Plan, Defendants are not obligated to provide coverage under that provision for Plaintiff's artificial disc replacement Surgery.

3. "To constitute a waiver of a requirement in an insurance policy, there must be . . . an actual intention to relinquish it or such conduct as warrants an inference of relinquishment." 6 *Couch on Insurance* § 85:2 (3d ed. 2015). Further, an "insurer will not be barred contrary to its actual intention unless the insured has been misled to his . . . prejudice into the honest belief that the waiver was intended or consented to, in which case an estoppel arises." *Id.* "[E]ven in insurance cases where the courts are inclined to grasp any circumstance which indicates an election to waive . . . there must be a clear, unequivocal, and decisive act showing a purpose or intention to waive, or the acts or conduct relied upon must involve some element of estoppel." *Id.* Based on the Court's factual findings that Defendants neither actually intended to waive their right to invoke the "Investigational" exclusion and that Ms. Sammons has not been misled to her prejudice into the honest belief that a waiver was intended or consented to, Ms. Sammons has failed to show that Defendants waived their rights to invoke the Investigational exclusion.

CONCLUSION

The Court construes Plaintiff's motion for summary judgment, Dkt. 14, and Defendants' motion for judgment on the record, Dkt. 17, as cross motions for judgment after a bench trial on

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the ERISA context, the Ninth Circuit has not yet decided which party bears the burden of proving that a policy exclusion applies after the claimant establishes that he or she is entitled to benefits. The Second and Seventh Circuit have, however, held that the burden shifts to the insurer to prove exclusions in ERISA cases. *See Mario v. P & C Food Markets, Inc.*, 313 F.3d 758, 765 (2d Cir. 2002) ("[A]s a matter of general insurance law, the insured has the burden of proving that a benefit is covered, while the insurer has the burden of proving that an exclusion applies."); *Santaella v. Metro. Life Ins. Co.*, 123 F.3d 456, 461 (7th Cir. 1997) ("[A]t trial the plaintiffs would bear the burden of proving [the plaintiffs'] entitlement to the benefits of the insurance coverage, and the defendant [insurance company] would bear the burden of establishing [the plaintiffs'] lack of entitlement because she falls within the 'exclusions' section of the insurance contract."). The Court concludes that it need not decide which party bears the burden of proving that the relevant exclusion applies because even if BCBSO bears that burden, BCSBO has met it.

an administrative record supplemented by stipulation. The Court DENIES Plaintiff's motion and GRANTS Defendants' motion.

IT IS SO ORDERED.

Dated this 23rd day of March, 2016.

/s/ Michael H. Simon
Michael H. Simon
United States District Judge